



K 970510

MAY 12 1997

510(k) SUMMARY
INNOFLUOR™ TOPIRAMATE REAGENT SET

Trade Name: INNOFLUOR™ Topiramate Assay System, which consists of three products that are packaged and sold separately: the INNOFLUOR™ Topiramate Reagent Set, the INNOFLUOR™ Topiramate Calibrator Set and the INNOFLUOR™ Topiramate Control Set.

Common or Usual Name: Topiramate Fluorescence Polarization Immunoassay

Classification Name: Fluorescence Polarization Immunoassay, Topiramate

The INNOFLUOR™ Topiramate Assay System is a fluorescence polarization immunoassay intended for the quantitative determination of total topiramate in serum or heparinized plasma. Topiramate serum or heparinized plasma concentrations are measured to aid in achieving appropriate therapy. The assay system is for use on the Abbott TDx® or the TDxFLx® analyzer.

Substantial equivalence has been demonstrated between the INNOFLUOR™ Topiramate Assay System, the INNOFLUOR™ Phenobarbital Assay System (INNOFLUOR™ Phenobarbital Reagent Set and INNOFLUOR™ Phenobarbital Calibrator Set), the Abbott Phenobarbital II Assay and Topiramate Gas Chromatography.

The technological characteristics, performance and intended use of the INNOFLUOR™ Topiramate Assay System are substantially equivalent to the INNOFLUOR™ Phenobarbital Assay System and the Abbott Phenobarbital II Assay with the exception of the specific anticonvulsant tested for by each method.

Topiramate concentrations measured by the INNOFLUOR™ Topiramate Assay System (INNOFLUOR™), on the Abbott TDx® analyzer, were compared with those measured by Topiramate Gas Chromatography (GC) on 117 patient samples from patients receiving topiramate therapy. Comparison of the patient sample results by linear regression analysis resulted in the regression equation: (INNOFLUOR™) = 0.985 x (GC) - 0.147, with a correlation coefficient of 0.9934, demonstrating equivalency of results.

Contact Person: Lynda M. Taylor
Vice President Quality Assurance and Regulatory Affairs

Date Prepared: 05/09/97

A3

Corporate Headquarters
6040 N. Cutter Circle, Suite 317, Portland, OR 97217-3935
Voice: 503-283-3911 • 800 547-3686 • Facsimile: 503-283-4058

European Operations
Z.A. des Petits Carreaux, 2, av. des Coquelicots, 94385 BONNEUIL-SUR-MARNE CEDEX FRANCE
Voice: 33 1 49 80 45 65 • Facsimile: 33 1 49 80 01 66